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I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	S81897
Date of Filing	30 July 1999
Applicant	GAYA LIMITED, a body corporate organising and existing in Dublin, Ireland of Unit 3, 70 Heather Road, Sandyford Industrial Estate, Dublin 18.

Dated this 4 day of March 2004.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

FORM NO. 1

IE990660

S990660

Request for the Grant of a Patent

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

☐ the grant of a patent under Part II of the Act

☒ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder

1. **Applicant(s)**

Name GAYA LIMITED

Address Unit 3, 70 Heather Road, Sandyford Industrial Estate, Dublin 18.

Description/Nationality Body corporate organising and existing in Dublin, Ireland.

2. **Title of Invention** **A SURGICAL DEVICE**

3. **Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)**

Previous Filing Date	Country in or for which Filed	Filing No.

4. **Identification of Inventor(s)**

Name(s) of person(s) believed by Applicant(s) to be the Inventor(s)

Address

5. **Statement of right to be granted a patent (Section 17(2)(b))**

990660

7. **Items accompanying this Request - tick as appropriate**

(vii) ☒ prescribed filing fee (£50.00)
(viii) ☐ specification containing a description and claims
☒ specification containing a description only
☒ drawings referred to in description or claims
(ix) ☐ an abstract
(x) ☐ copy of previous application(s) whose priority is claimed
(xi) ☐ translation of previous application whose priority is claimed
(xii) ☐ Authorisation of Agent (this may be given at 8 if this Request is signed by the Applicant(s)

7. **Divisional Application(s)**

The following information is applicable to the present application which is made under Section 24:-

Earlier Application No. ..... Filing Date .....

8. **Agent**

The following is authorised to act as agent in all proceedings connection with the obtaining of a patent to which this request relates and in relation to any patent granted:-

MACLACHLAN & DONALDSON, 47 Merrion Square, Dublin 2

9. **Address for Service (if different to that at 8)**

MACLACHLAN & DONALDSON, at their address as recorded for the time being in the Register of Patent Agents (Rule 92)

Signed Name(s) GAYA LIMITED

By .....
MACLACHLAN & DONALDSON, Applicants' Agents

Date July 30 1999

S81897
APPLICATION No. S990660

A SURGICAL DEVICE

The present invention relates to a surgical device for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and sealing the incision with an access port. The access port enables laproscopic and hand or instrument assisted surgery to be performed.

A sleeve forming such a port is shown in PCT Patent Application No. PCT/IE94/00045 entitled "Apparatus for use in surgery". The access port sleeve shown is used to create a controlled pressurized environment within the sleeve while allowing a surgeon's arm to pass through the sleeve. During surgery, gas is pumped into the body cavity around the surgery site and the sleeve prevents gas escaping while allowing the surgeon to operate using minimally invasive surgery techniques. The application shows a sleeve having a flange at a distal end provided with adhesive for adhering the device to a patient's body or alternatively a mounting ring to surround the incision in a patient's body. While providing a suitable apparatus for performing such surgery the device described suffers from the principle disadvantage that in use, the sleeve protrudes upwardly from the patient and may interfere with the surgical team's activities. Additionally, the sleeve must be sealed against the surgeon's upper forearm by clamping the device to the arm sufficiently tightly to avoid gas leak around the area of the seal. This presents the surgeon with a problem both in sealing the sleeve and in subsequent mobility.

A further problem associated with the use of sleeves of the kind described is that a phenomenon known as "tenting" may occur. "Tenting" means that when the sleeve is adhered to the patient's skin or to a surgical drape and gas is induced into the patients abdominal cavity, there is a tendency for the sleeve to fill with gas and to pull away from the patient. A still further problem associated with the use of such sleeves is that repeated insertion of surgical devices or the surgeons hand can cause unacceptably high trauma

levels around the incision. This is particularly problematic when a surgeon attempts to remove an intact specimen or a hard organ.

There is therefore a need for a surgical device, which will overcome the aforementioned problems.

Accordingly, there is provided a surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an incision, the device being formed to define a sleeve access port for insertion into the incision and having:-

mounting means for locating and securing the device in position on a patient;

sealing means to prevent substantial leakage of gas from the body cavity; and

a retractor to limit contact between the sleeve and the incision when in use.

Thus, contact with the incision is limited thereby reducing patient trauma and greatly improving the ease with which instruments or a surgeons hand may be inserted.

In one arrangement, the retractor is provided as a deformable tube.

Preferably, the tube has at opposing ends a proximal ring and a distal ring.

Preferably, the proximal and distal rings are formed for substantially airtight engagement with the sleeve and with the patients abdomen.

In one arrangement the or each ring incorporates an adhesive portion for fixing the ring in position.

Preferably, the distal ring is formed for substantially airtight engagement with the sleeve and with the patients internal abdominal wall.

Ideally engagement between the proximal ring and sleeve is provided by a skirt carried on the sleeve and having a rim formed for releasable engagement to the ring.

In one arrangement the ring and skirt are integrally formed.

In one arrangement the skirt has an integrally formed glove or pocket for receiving a surgeons hand or surgical instrument.

In one arrangement the skirt has a recessed or undercut receiver formed for engagement with a ring or a surgeons glove.

In a preferred embodiment, the proximal ring incorporates a flexible gas retaining ring extending down from the proximal ring and formed for engagement against a patients skin when in position to define a gas retention chamber.

Preferably, the gas retaining ring is inflatably movable between an insertion position and an in use position.

In one arrangement, the gas retaining ring is provided by a collapsible bellows ring.

In a particularly preferred embodiment, the device incorporates a retractor-positioning device.

Ideally, the retractor-positioning device has means for releaseably engaging the proximal ring and the distal ring.

Preferably, the means for engaging the proximal ring and the distal ring are movable between a retracted position and a locating position.

Ideally, the means for engaging the proximal ring and the distal ring are telescopically movable.

According to one aspect of the invention the proximal ring supports a flexible web, said web in turn defining a hole for receiving the sleeve.

According to another aspect of the invention the device incorporates a collapsible support scaffold, the scaffold being formed for supporting the device in an operative state and collapsible to provide a surgeon free access to the incision.

The invention will now be described more particularly with reference to the accompanying drawings, which show, by way of example only, some embodiments of a surgical device in accordance with the invention, in which:-

Fig. 1 is a sectional view of a surgical device in accordance with the invention in position on a patient;

Fig. 2 is front view of a sleeve forming part of the invention;

Fig. 3 is a perspective view of a retractor forming part of the invention;

Fig. 4 is a front view of a retractor-positioning device forming part of the invention;

Fig. 5 is a sectional view of another embodiment of a surgical device in accordance with the invention in position on a patient;

Fig. 6 is a sectional view of the device of Fig. 5 with a surgeons hand inserted;

Fig. 7 is a sectional view of a further embodiment of a surgical device in accordance with the invention in position on a patient;

Fig. 8 is a sectional view of the device of Fig. 7 with a surgeons hand inserted;

Fig. 9 is a sectional view of a still further embodiment of a surgical device in accordance with the invention;

Fig. 10 is a sectional view of another surgical device in accordance with the invention;

Fig. 11 is a sectional view similar to that shown in Fig. 10 in position on a patient;

Fig. 12 is a sectional view of another surgical device in accordance with the invention in position on a patient;

Fig. 13 is a sectional view of a further surgical device in accordance with the invention in position on a patient;

Fig. 14 is a top view of the surgical device of Fig. 13;

Fig. 15 is a sectional view of another surgical device in accordance with the invention in an insertion position on a patient; and

Fig. 16 is a sectional view of the surgical device of Fig. 15 in an operating position on a patient.

Referring to the drawings, and initially to Figs. 1 to 4 there is illustrated a surgical device according to the invention, indicated generally by the reference numeral 1. The surgical device 1 is formed for use in minimally invasive surgery of the type using an inflated body cavity indicated generally by the reference numeral 2. The cavity 2 is accessible to a surgeon through an access port, defined by a sleeve 4, which passes through an incision in a patient's abdominal wall 3. The sleeve 4 is connected to a retractor indicated generally by the reference numeral 5 which atraumatically retracts the incision. The retractor 5 is

pressed against the incision to protect it from contact as a surgeon introduces or withdraws a hand, surgical device or body tissue. The retractor 5 is inserted using a retractor-positioning device indicated generally as 6, which will be described in more detail below.

Referring now to Fig. 2, sealing means is provided for the device 1 by the sleeve 4 which is in this case of the type known and marketed by Medtech Ltd., as an INTROMIT ^{R} sleeve. The sleeve 4 has an entrance opening 41. A flexible elongate inner sleeve 42 extends downwardly from the opening 41 and terminates away from the opening with a taut valve 43. A feathered valve 44 is also suspended from the opening inside the inner sleeve 42. The sleeve 4 also has a skirt 45 extending downwardly from the opening 41 outside the inner sleeve 42. The skirt 45 has a flexible rim 46 for connection in an airtight manner to the retractor 5.

The retractor 5 as shown in Fig. 3 has a proximal ring 51 for receiving the flexible rim 46 and a distal ring 52 connected to the proximal ring 51 with a flexible incision engaging retractor wall 53. The proximal ring 51 and the distal ring 52 are positioned on the patient using the retractor-positioning device 6 as shown in Fig. 4. The retractor-positioning device 6 has means for engaging the proximal ring 51 provided by a pair of oppositely directed telescopic arms 61carried on an introduction shaft 63. The shaft 63 also carries means for engaging the distal ring provided in this case by pivotally moveable distal arms 63.

In use, an incision is made in the abdominal wall 3. The distal ring 52 and the proximal ring 51 are engaged on the respective arms 62, 61 with the arms 62, 61 in a retracted position (not shown) having the arms 62, 61 close to the shaft 63. The proximal ring 51 is then positioned on the patient by telescopically extending the arms 61. The distal arms 62 and portion of the shaft 63 are then passed through the incision into the cavity 2. The distal ring 52 is moved into position when in the cavity 2 by pivoting the oppositely directed arms 62 away from the shaft 63 so that the ring 52 surrounds the incision. The ring 51 is disengaged from the arms 61 causing it to open against the abdomen wall. The arms 62 are

disengaged from the ring 52 by pulling upward. By positioning the retractor in this way a variety of incision depths can be accommodated.

When the retractor 5 has been positioned on the patient the flexible rim 46 is then deformed by the surgeon to engage on and around the proximal ring 51 in an air tight manner. The body cavity is then inflated and when inflated the flexible elongate inner sleeve 42 is allowed to extend downwardly from the opening 41 with the taut valve 43 inserted into the body cavity. The feathered valve 44 is also suspended from the opening 41 inside the inner sleeve 42 and above the incision. The gas pressure within the cavity inflates the skirt 45. The seal of the rim 46 and the ring 51 prevents air pressure from escaping. The surgeon can then operate on the patient and the constant and controlled distance between the sleeve and the retractor prevents unnecessary contact with the incision thereby reducing overall patient trauma and providing the surgeon with a greater range of movement unencumbered by the incision wall.

Referring now to Figs. 5 and 6 there is illustrated another surgical device according to the invention, indicated generally by the reference numeral 100 in which parts similar to those described in Figs. 1 to 4 are identified by the same reference numerals generally. In this embodiment, the device has an extended proximal ring 151. The proximal ring 151 supports a highly flexible web 152 which in turn defines an opening through which a sleeve 153 passes. The sleeve 153 is terminated in a taut valve 43 above the incision. The operation of this device is similar to that described above. It will be appreciated that the retractor may also be manually positioned on the operating site. By providing the device in this way the taut valve is housed above the incision thereby allowing a surgeon greater visibility as well as eliminating the need to insert any valves within the body cavity. Additionally, the valve will not travel with the surgeon's wrist during insertion and as a low sealing force is required, the surgeon suffers little compression on the arm during insertion.

Referring now to Figs. 7 and 8 there is illustrated a further surgical device according to the invention, indicated generally by the reference numeral 700 in which parts similar to those

described in Figs. 1 to 6 are identified by the same reference numerals generally. In this embodiment the skirt 45 is supported by a collapsible scaffold structure 701. The scaffold structure 701 is in turn carried on the proximal ring 51.

In use, when the device 701 has been positioned on a patient the skirt 45 is supported by the structure 701 (See Fig. 7). As a surgeon inserts a hand or instrument into the sleeve 4 the structure collapses (See Fig. 8) to provide free access and good operating site visibility for the surgeon.

Referring now to Fig. 9 there is illustrated another a surgical device according to the invention, indicated generally by the reference numeral 900. In this embodiment the skirt 45 has an integrally formed surgeons glove 901. In this way the need for valves and sleeves is eliminated while still maintaining the required pressure and allowing the surgeon a full range of movement.

Referring now to Figs. 10 and 11 there is illustrated another surgical device according to the invention, indicated generally by the reference numeral 1000 in which parts similar to those described in Figs. 1 to 9 are identified by the same reference numerals generally. Here the proximal ring 51 incorporates a flexible base ring 1001. The base ring 1001 is formed to lie against a patient's exterior when in position and to define a gas retention chamber 1002 with the patient's exterior. Thus, gas escaping from the body cavity through the incision and outside the sleeve 4 is trapped in the chamber 1002.

Fig. 12 illustrates another a surgical device according to the invention, indicated generally by the reference numeral 1200. In this embodiment a taut valve 1201 is formed from an elasticised portion of a tapered sleeve 1204 . Oppositely directed connecting limbs 1202 extend outwardly from the valve 1201 and attach to a proximal ring 1203. In use, the limbs 1202 stretch the sleeve 1204 causing the sleeve 1204 to narrow the taut valve 1201 and seal. When a surgeon inserts a hand or surgical instrument the limbs 1202 are deflected to allow access. When the hand or instrument is removed, the limbs re-establish the seal as before.

Referring now to Figs. 13 and 14 there is illustrated another surgical device according to the invention, indicated generally by the reference numeral 1300 in which parts similar to those described in Figs. 1 to 12 are identified by the same reference numerals generally. In this embodiment, the sleeve 4 extends downwardly from an oval semi-rigid proximal ring 1301. The ring 1301 in turn is carried on an inflatable ring 1302, which is formed for inflation by an inflator 1303. In use, the device is positioned on a patient and the ring 1302 is inflated. The degree of retraction required is controlled by the pressure in the ring 1302 as greater pressure will force the sleeve 4 against the incision. As the proximal, distal and inflatable rings are oval even pressure is applied at all points during retraction greatly reducing patient trauma. The inflation of the ring 1302 draws the sleeve 4 against the incision and prevents loss of pneumoperitoneum.

Figs. 15 and 16 illustrate another surgical device according to the invention indicated as 1500, which is similar in operation to the embodiment shown in Figs. 13 and 14. In this embodiment ring 1302 is replaced with a compressible bellows ring 1501. The bellows ring 1501 has a one way valve 1502. In use, the compressed bellows ring 1501 is positioned on a patient. The ring is drawn up to allow air to inflate the bellows ring 1501 through the valve 1502. This inflation retracts the incision to the required degree and the valve 1502 prevents the air from escaping and the incision from closing. The incision can be released only by activation of the valve 1502 by the surgeon.

Thus, by the relatively simple expedient of providing an integrated wound or incision retractor in the access port, trauma is reduced thereby greatly easing patient suffering and accelerating postoperative recovery. Additionally, the invention provides a greater range of movement to the surgeon allowing the device to be used in a wider variety of surgical applications.

It will of course be understood that the invention is not limited to the specific details described herein, which are given by way of example only, and that various modifications and alterations are possible within the scope of the invention.

MACLACHLAN & DONALDSON,
Applicant's Agents,
47, Merrion Square,
DUBLIN 2.

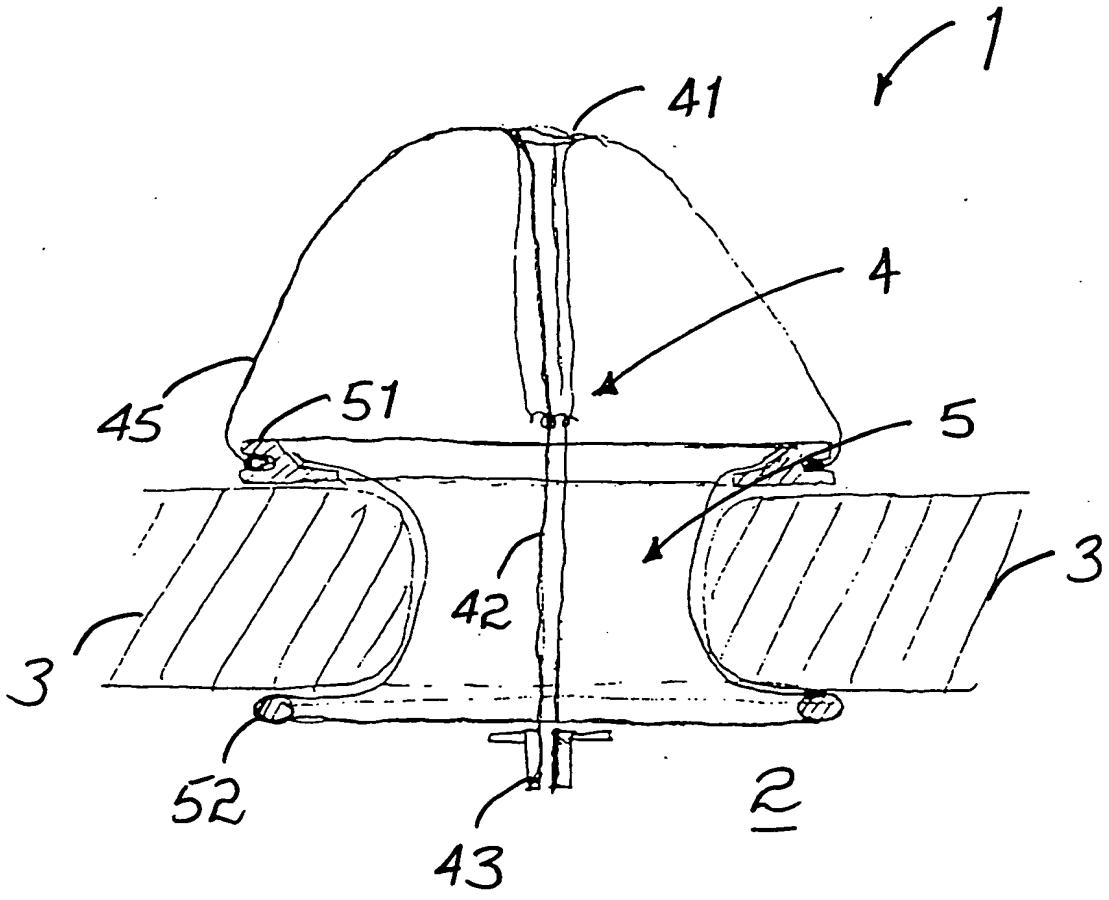

Fig. 1

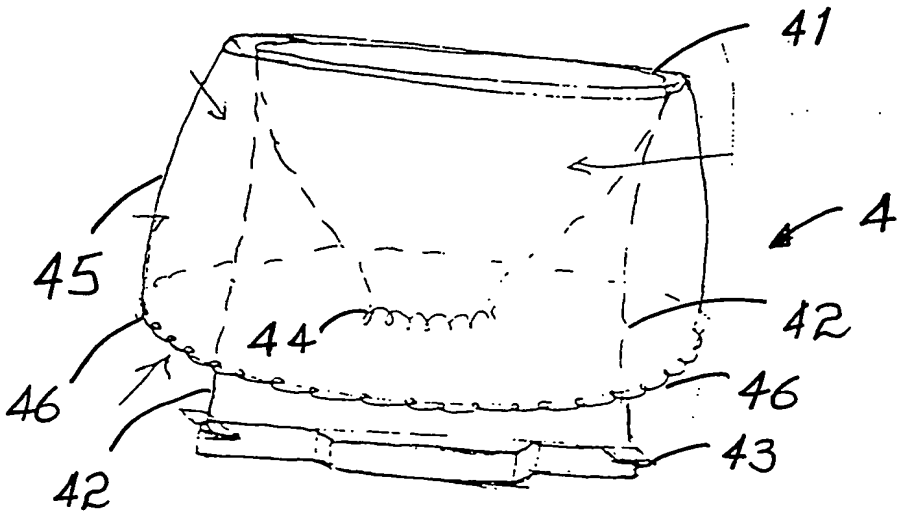

Fig. 2

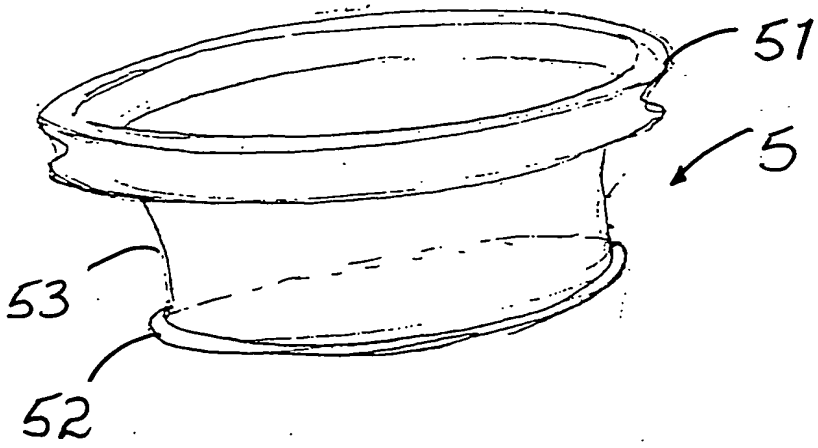

Fig. 3

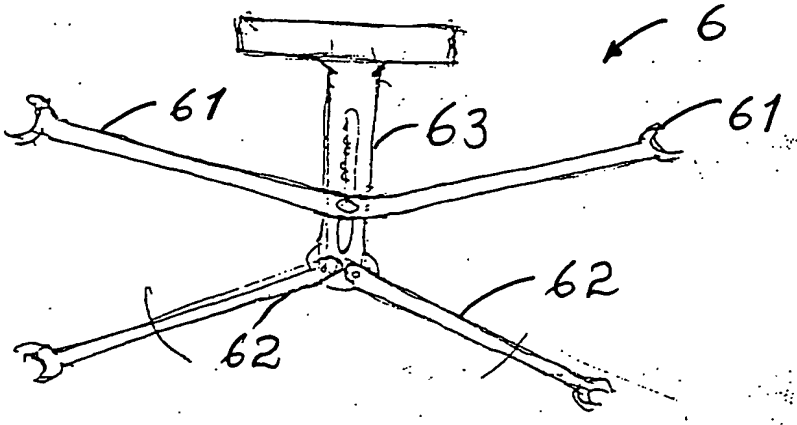

Fig. 4

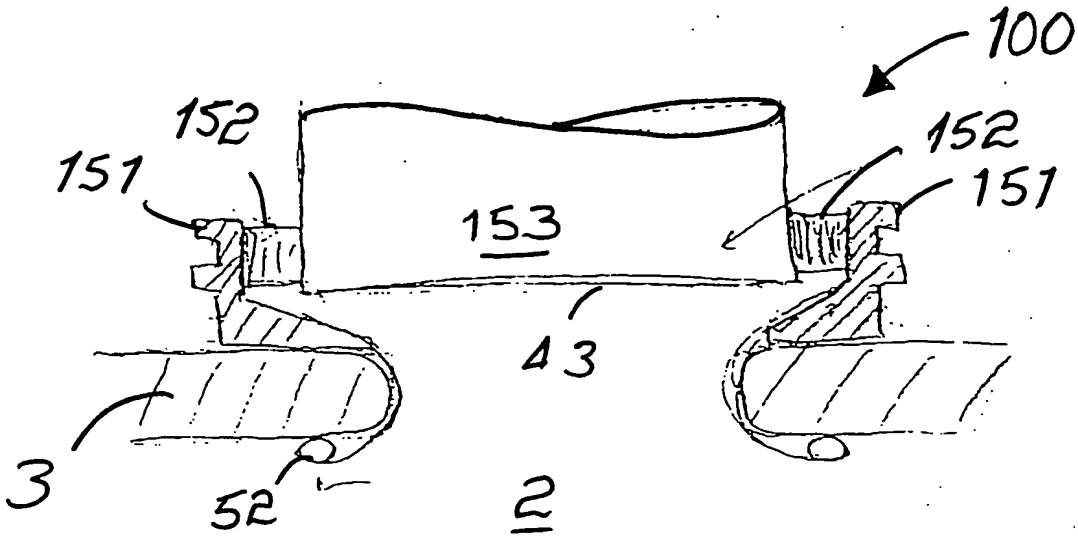

Fig. 5

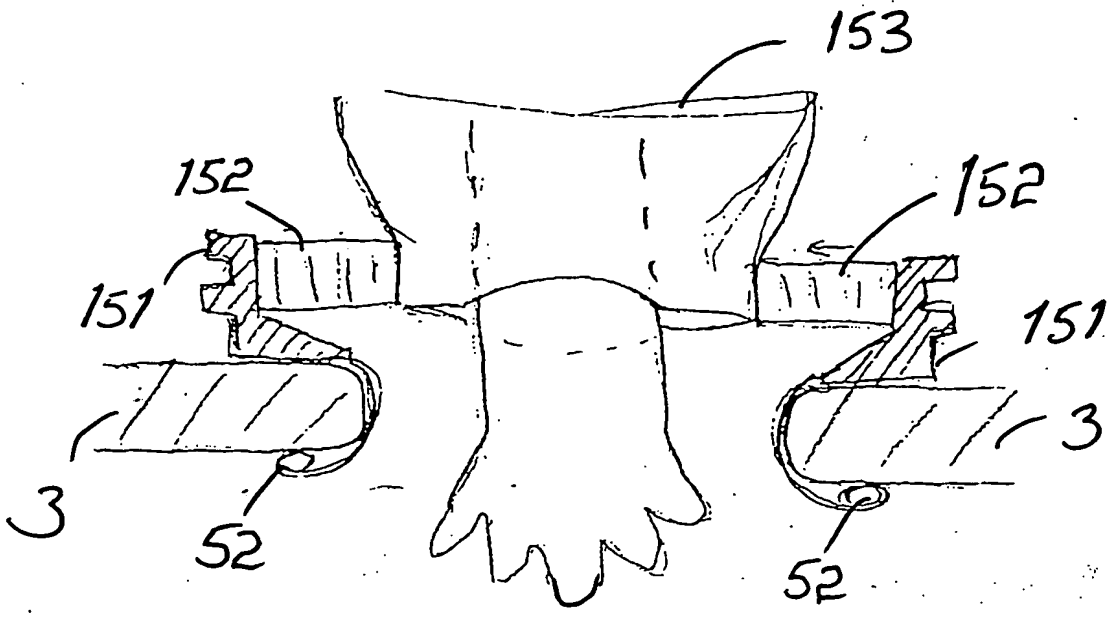

Fig. 6

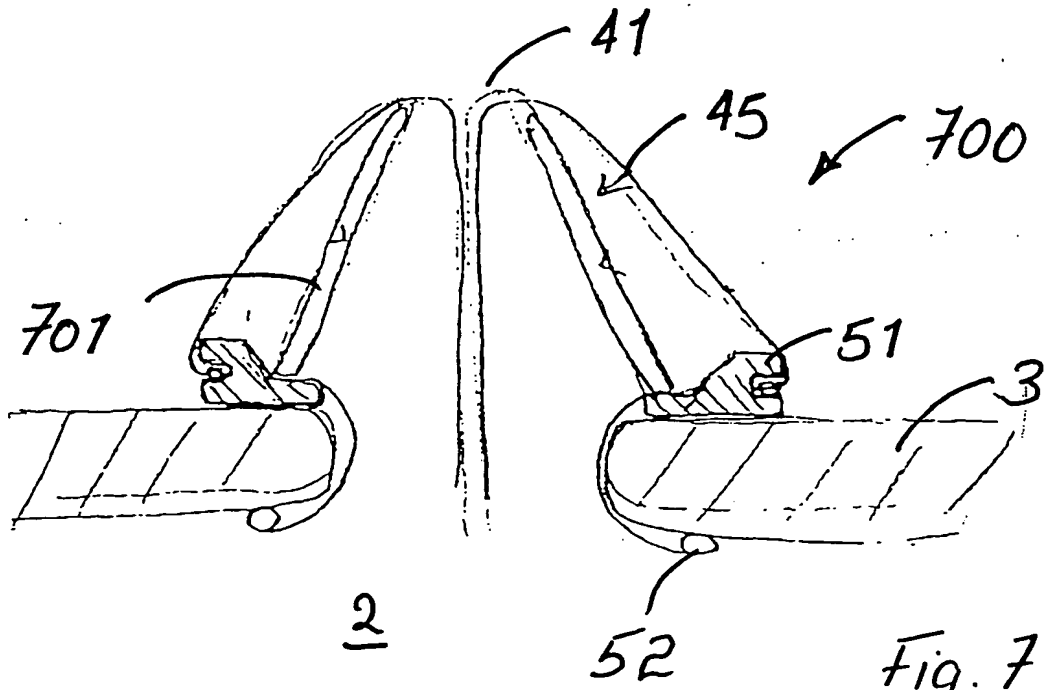

Fig. 7

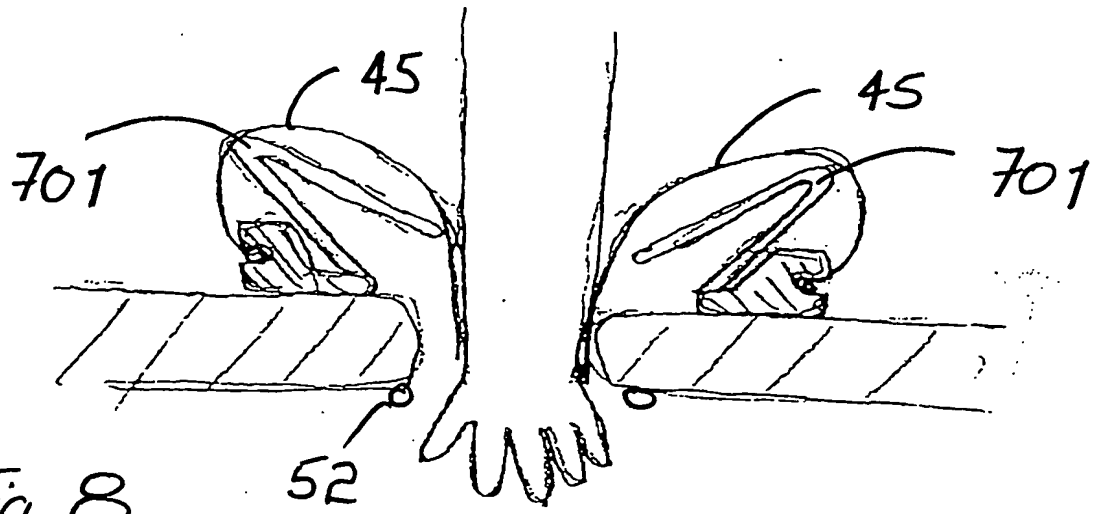

Fig. 8

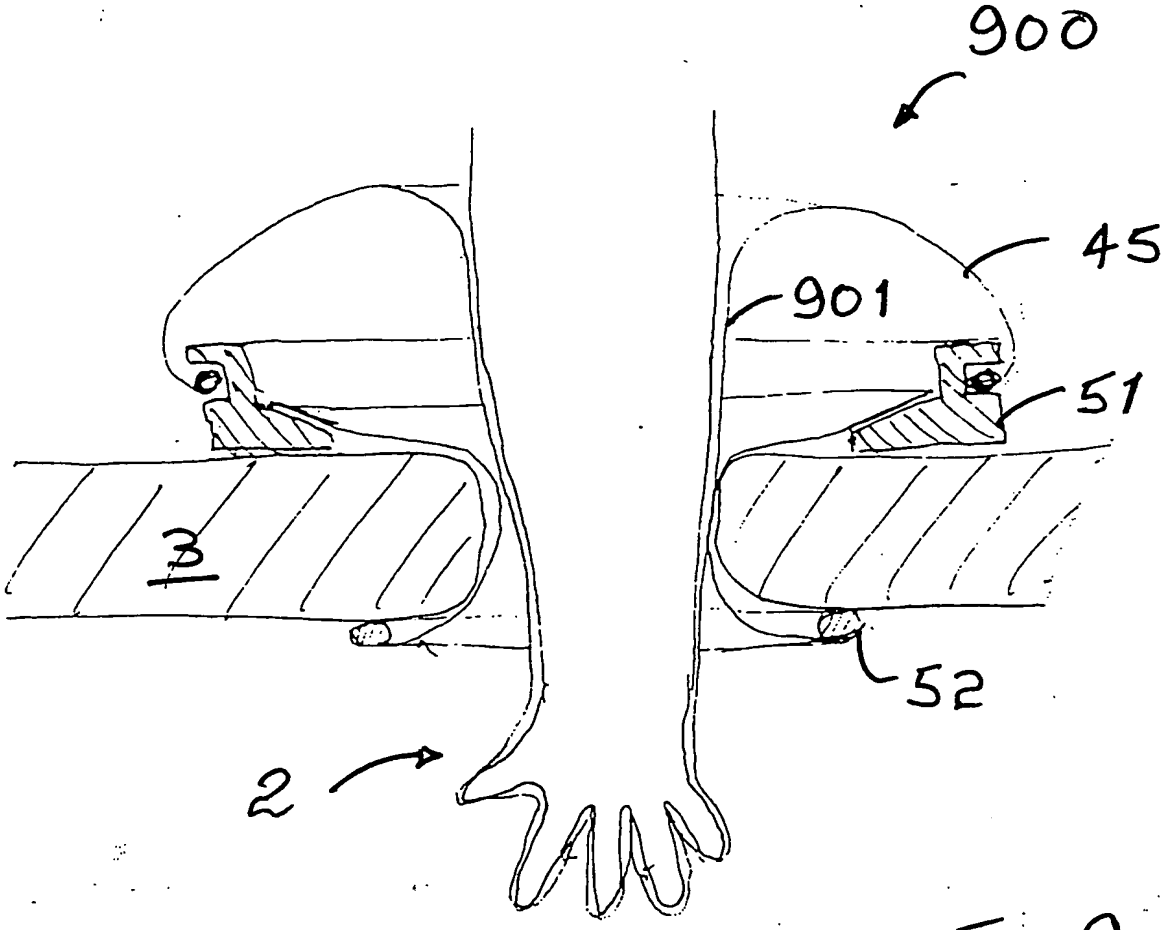

Fig. 9

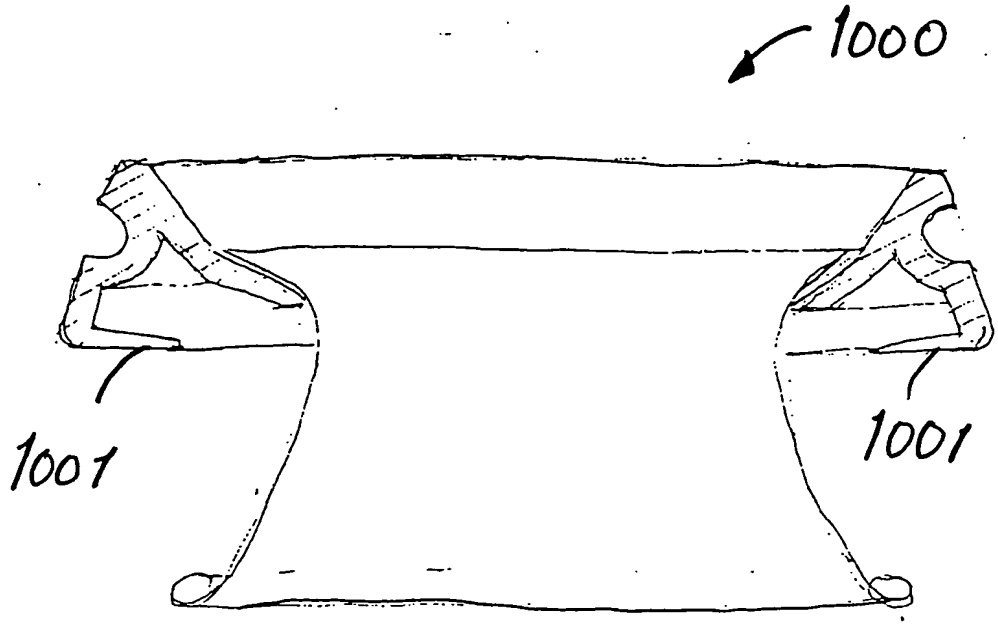

Fig. 10

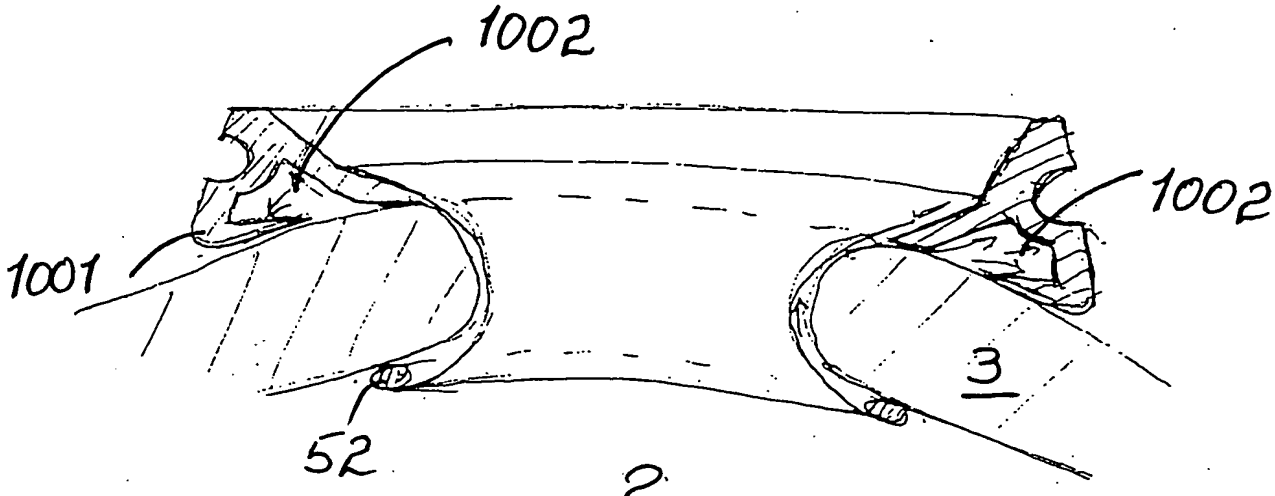

Fig. 11

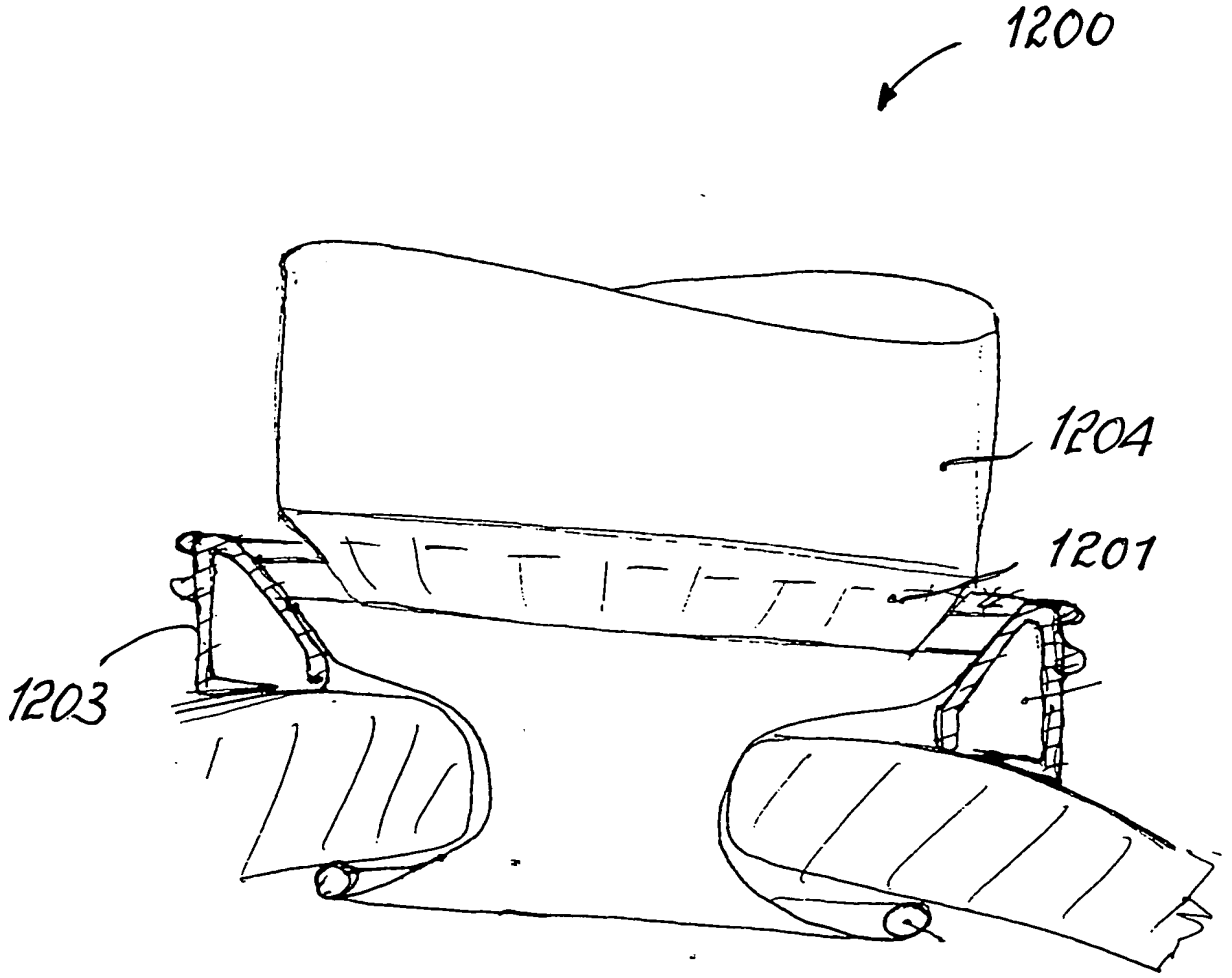

Fig. 12

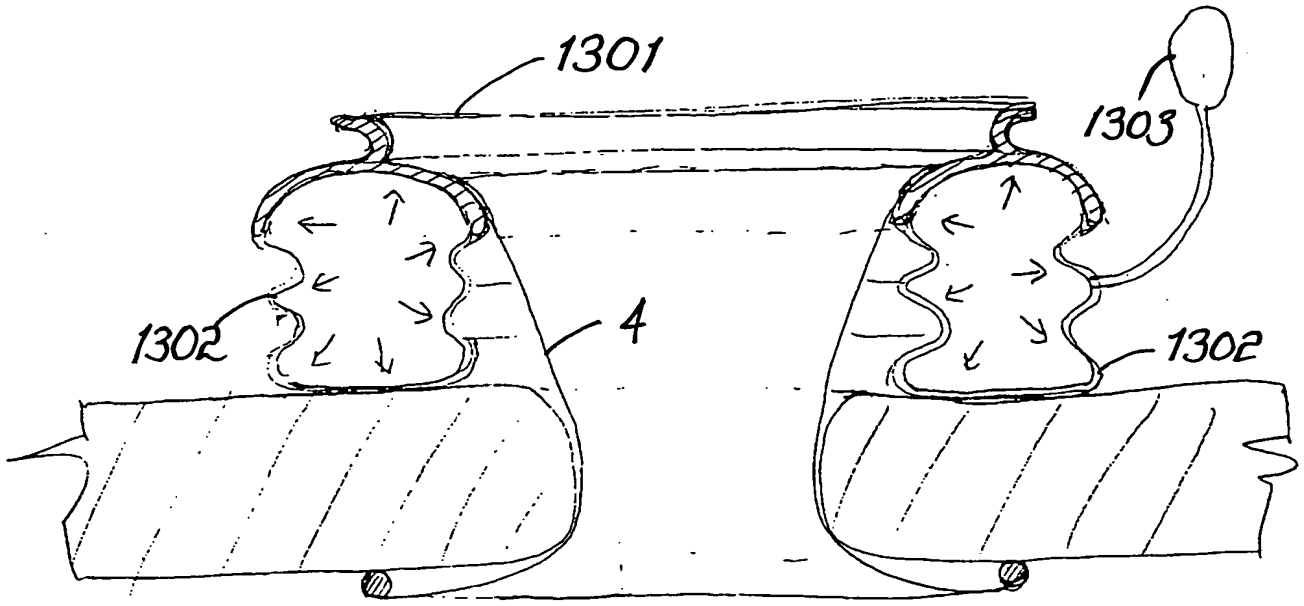

Fig. 13

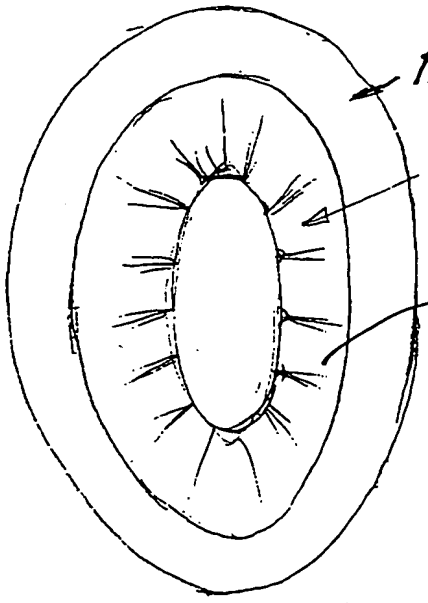

Fig. 14

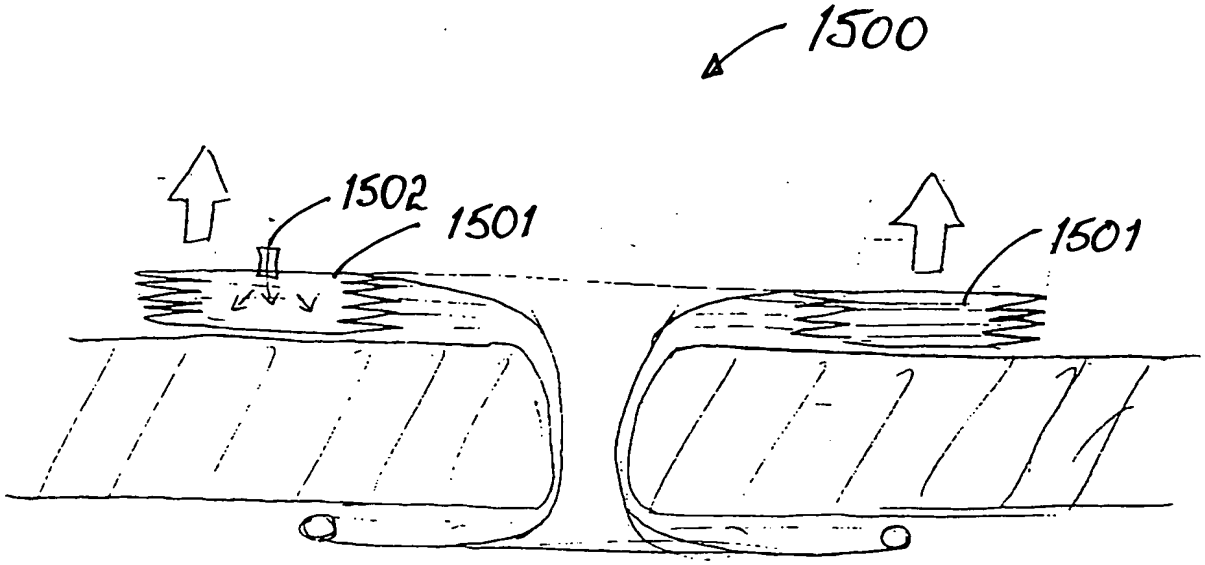

Fig. 15

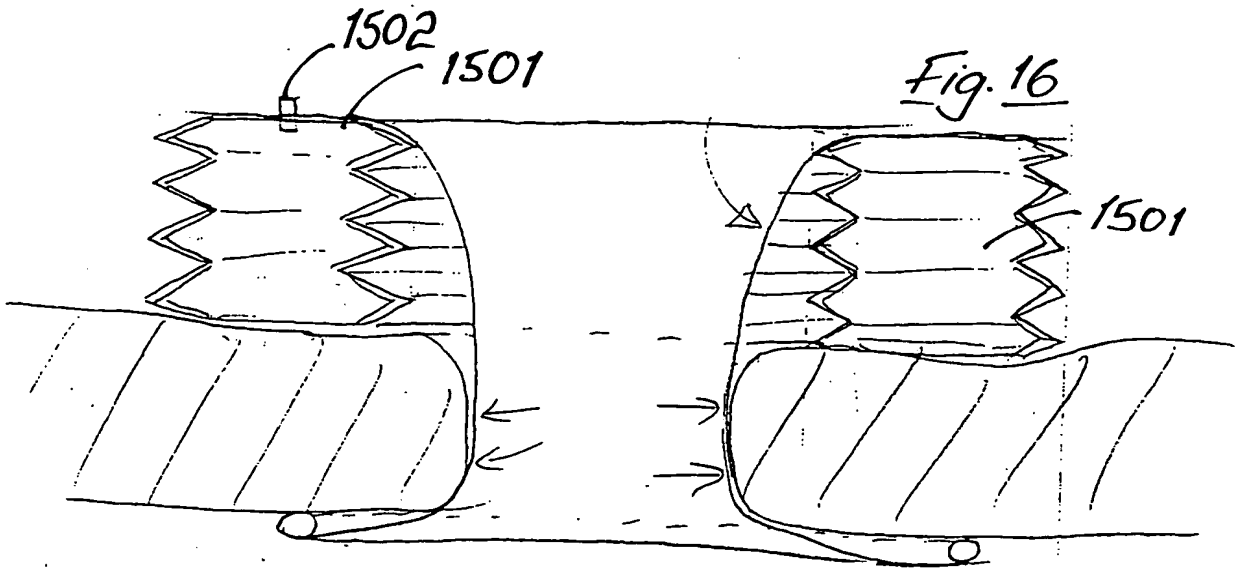

Fig. 16